

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the 2003 list were published in the Federal Register in January 2003.

### New Approvals

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#### NADA Number: 141-210

Trade Name: Genesis™ Topical Spray  
Ingredients: Triamcinolone acetonide  
Sponsor: RMS Laboratories, Inc.  
Approval Date: November 4, 2002  
Status: Prescription only  
Route: Topical  
Species: Dogs  
Drug Form: Liquid (solution)  
Concentration: 0.15 milligram per milliliter  
Indications: For the control of pruritus associated with allergic dermatitis.  
Patent Number: 6,300,326 Expiration date: November 2, 2014  
Exclusivity: 3 years

21CFR 524.2482 & 510.600

#### ANADA Number: 200-340

Pioneer Product: 140-841  
Trade Name: Privermectin™  
Ingredients: Ivermectin  
Sponsor: First Priority, Inc.  
Approval Date: December 4, 2002  
Status: Over-the-counter  
Route: Topical  
Species: Cattle  
Drug Form: Liquid (solution)  
Concentration: 5 milligrams per milliliter  
Indications: For the treatment and control of :  
**Gastrointestinal Roundworms**  
*Ostertagia ostertagi* (adults and L<sub>4</sub>) (including inhibited stage), *Haemonchus placei* (adults and L<sub>4</sub>); *Trichostrongylus axei* (adults and L<sub>4</sub>); *T. colubriformis* (adults and L<sub>4</sub>); *Cooperia spp.* (adults and L<sub>4</sub>); *Strongyloides papillosus* (adults); *Oesophagostomum radiatum* (adults and L<sub>4</sub>); *O. venulosum* (adults only); *Trichuris spp.* (adults). Also used to control infections of gastrointestinal roundworms: *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.  
**Lungworms**  
*Dictyocaulus viviparus* (adults and L<sub>4</sub>)  
**Cattle Grubs** (parasitic stages)  
*Hypoderma bovis*; *H. lineatum*  
**Mites**  
*Sarcoptes scabiei* var. *bovis*  
**Lice**  
*Linognathus vituli*; *Haematopinus eurytenuis*; *Damalinia bovis*; *Solenopotes capillatus*  
**Horn Flies**  
*Haematobia irritans*  
Tolerance: 21CFR 556.344 Ivermectin: A tolerance is established for 22,23-dihydroavermectin B<sub>1a</sub> (marker residue) in liver (target tissue) as 100 parts per billion and 10 parts per billion in muscle.  
Withdrawal: 48 days

21CFR 524.1193

## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-303

Pioneer Product: 111-636  
Trade Name: Lincomycin Hydrochloride Soluble Powder  
Ingredients: Lincomycin hydrochloride  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: October 1, 2002  
Status: Over-the-counter  
Route: Oral, via drinking water  
Species: Swine, broiler chickens  
Drug Form: Powder (soluble)  
Concentration: Each 40 gram packet contains lincomycin hydrochloride equivalent to 16 grams of lincomycin.  
Indications: Swine: For the treatment of dysentery (bloody scours).  
Broiler chickens: For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.  
Tolerance: 21CFR 556.360 Lincomycin: Swine – Tolerances for residues of lincomycin as 0.6 part per million in liver and 0.1 part per million are established. Chickens – A tolerance for residues of lincomycin in chickens is not required.  
Withdrawal: Zero days

21CFR 520.1263c

### ANADA Number: 200-348

Pioneer Product: 140-841  
Trade Name: Ecomectin  
Ingredients: Ivermectin  
Sponsor: ECO LLC  
Approval Date: November 15, 2002  
Status: Over-the-counter  
Route: Topical  
Species: Cattle  
Drug Form: Liquid (solution)  
Concentration: 5 milligrams per milliliter  
Indications: For the treatment and control of:  
**Gastrointestinal Roundworms**  
*Ostertagia ostertagi* (adults and L<sub>4</sub>) (including inhibited stage), *Haemonchus placei* (adults and L<sub>4</sub>); *Trichostrongylus axei* (adults and L<sub>4</sub>); *T. colubriformis* (adults and L<sub>4</sub>); *Cooperia* spp. (adults and L<sub>4</sub>); *Strongyloides papillosus* (adults); *Oesophagostomum radiatum* (adults and L<sub>4</sub>); *O. venulosum* (adults only); *Trichuris* spp. (adults). Also used to control infections of gastrointestinal roundworms: *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.  
**Lungworms**  
*Dictyocaulus viviparus* (adults and L<sub>4</sub>)  
**Cattle Grubs**(parasitic stages)  
*Hypoderma bovis*; *H. lineatum*  
**Mites**  
*Sarcoptes scabiei* var. *bovis*  
**Lice**  
*Linognathus vituli*; *Haematopinus euryesternus*; *Damalinia bovis*; *Solenopotes capillatus*  
**Horn Flies**  
*Haematobia irritans*  
Tolerance: 21CFR 556.344 Ivermectin: A tolerance is established for 22,23-dihydroavermectin B<sub>1a</sub> (marker residue) as 100 parts per billion (ppb) in liver and 10 ppb in muscle.  
Withdrawal: 48 days

21CFR 524.1193 & 510.600

## Actions Taken by FDA Center for Veterinary Medicine

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**ANADA Number: 200-313**

Pioneer Product: 112-049  
Trade Name: Levamisole Hydrochloride Soluble Pig Wormer  
Ingredients: Levamisole hydrochloride  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: October 25, 2002  
Status: Over-the-counter  
Route: Oral, via drinking water  
Species: Swine  
Drug Form: Powder (soluble)  
Concentration: 18.15 grams levamisole hydrochloride per bottle  
Indications: For the treatment effective against the following nematode infections:  
Large roundworms (*ascaris suum*), nodular worms (*Oesophagostomum spp.*), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*).  
Tolerance: 21CFR 556.350 Levamisole hydrochloride: A tolerance of 0.1 part per million is established for negligible residues in the edible tissues.  
Withdrawal: 3 days

21CFR 520.1242a

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### Change of Sponsor

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<b>NADA Number:</b>	<b>010-092</b>	<b>010-346</b>	<b>012-123</b>	<b>035-157</b>	<b>035-455</b>
	<b>035-456</b>	<b>038-241</b>	<b>038-242</b>	<b>038-624</b>	<b>038-661</b>
	<b>041-955</b>	<b>044-756</b>	<b>055-059</b>	<b>093-515</b>	<b>095-218</b>
	<b>100-218</b>	<b>101-690</b>	<b>107-506</b>	<b>118-032</b>	<b>118-979</b>
	<b>120-615</b>	<b>126-504</b>	<b>200-050</b>	<b>200-103</b>	<b>200-144</b>

From: Bimeda, Inc.  
To: Cross Vetpharm Group, Ltd.  
Broomhill Rd.  
Tallaght, Dublin 24, Ireland  
Drug labeler code: 061623

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### Addition of Sponsor

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Name: ECO LLC  
8209 Hollister Ave.  
Las Vegas, NV 89131  
Drug labeler code: 066916

Name: RMS Laboratories, Inc.  
1903 East First St.  
Vidalia, GA 30474  
Drug labeler code: 067292

## **Actions Taken by FDA Center for Veterinary Medicine**

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### **Change of Sponsor Name, Address**

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From: Micro Chemical, Inc.

To: Micro Beef Technologies, LTD  
P.O. Box 9262  
Amarillo, TX 79105  
Drug labeler code: 047126

From: Pennfield Oil Co.  
14040 Industrial Rd.  
Omaha, NE 68137

To: Pennfield Oil Co.  
14040 Industrial Rd.  
Omaha, NE 68144  
Drug labeler code: 053389